# 5/ IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

Francesco MEHLEM et al.

Serial No.: 09/831,816 Art Unit: 1654

Filed: January 5, 2000 Examiner: R. Teller

For: PHARMACEUTICAL COMPOSITION

RECEIVED

#### INFORMATION DISCLOSURE STATEMENT

DEC 0 5 2003

TECH CENTER 1600/2900

Commissioner of Patents PO Box 1450 Alexandria, VA 22314-1450

Sir:

Pursuant to Rules 56 and 98, Applicants hereby call the attention of the Patent Office to the references listed on the attached Form PTO 1449.

## New References

All but one of these enclosed references are US Patent Application Publication 2003/0162721 (US Patent Application serial no. 09/462,155 having an inventor in common with the present application) and the references cited in the international stage or national stage of copending US Patent Application serial no. 09/462,155.

#### BE 775775

Another reference cited on the attached Form PTO 1449 is BE '775 cited in the International Stage Search Report of the International Stage of the present application and cited in an IDS filed May 15, 2001 in the present application. A copy of BE '775 need not be supplied because the Examiner should already have it since it was cited in the International Stage of the present application. A recent computer search for equivalents was conducted but found none.

The Examiner did not return the PTO-Form 1449 from the May 15, 2001 IDS to indicate BE '775 was considered. Applicants request BE '775 be indicated as considered. BE '775 was designated as an "A" reference on the International Search Report and according to MPEP Section 609 A(3) (a copy of which is attached) this suffices as a concise statement of relevance for this non-English language reference. Moreover, Applicants discuss the reference at pages 2 and 3 of the previously submitted certified English language translation of the present application.

## Conclusion

Applicants present these references so that the Patent Office may, in the first instance, determine any relevancy thereof to the presently claimed invention, see <u>Beckman Instruments, Inc. v. Chemtronics, Inc.</u>, 439 F.2d 1369, 1380, 165 USPQ 355, 364 (5th Cir. 1970). Also see Patent Office Rules 104 and 106. Applicants respectfully request that these references be expressly considered during the prosecution of this application and made of record herein and appear among the "References Cited" on any patent to issue from this application.

This IDS is submitted after an action on the merits but before a final Office action, a notice of allowance or an action that otherwise closes prosecution. Thus, under 37 CFR 1.97(c) it is accompanied by a check for the \$180 fee under 37 CFR 1.17(p).

The Commissioner of Patents and Trademarks is hereby authorized to charge any additional fee (or credit any overpayment) to Deposit Account No. 19-4375.

By:

APV/pgw ATTORNEY DOCKET NO. APV31199

Date: Dec. 1, 2004

Anthony P. Venturino Registration No. 31,674

Respectfully submitted,

STEVENS, DAVIS, MILLER & MOSHER, L.L.P. 1615 L STREET, N.W., SUITE 850

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)														
Rajewski et al, "Pharmaceutical Applications of Cyclodextrins. 2. In Vivo Drug Delivery", Journal of Pharmaceutical Sciences, Vol. 85, No. 11, pp. 1142-69, November 1996														
	Astaldi, "Peptichemio: A Multifaceted Antiblastic Drug", Wadley Medical Bulletin, Vol. 5, No. 3, pp. 303-326 (1975)													
14	Hansson et al, "Cytotoxicity and DNA Cross-Linking Induced By Peptide Conjugated m-L-Sarcolysin In Human Melanoma Cells", Anticancer Research, Vol. 11, pp. 1725-30 (1991)													
	Hug et al, "A Phase II Study of Peptichemio In Advanced Breast Cancer", Cancer, Vol. 45, pp. 2524-28 (1980)													
	Medina et al, "Chlorpheniramine Inhibits The Synthesis of Ornithine Decarboxylase and the Proliferation of Human Breast Cancer Cell Lines", Breast Cancer Research and Treatment, Vol. 35, pp. 187-94 (1995)													
	US Patent Application Publication 2003/0162721 to Mehlem et al, published Aug. 28, 2003 (Serial No. 09/462,155; International Filing Date July 7, 1998; 102(e) date Jan. 5, 2000)													
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EXAMINER: Initial if citation is considered, draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Second, 37 CFR 1.98(c) states that when the disclosures of two or more patents or publications listed in an information disclosure statement are substantively cumulative, a copy of one of the patents or publications may be submitted without copies of the other patents or publications provided that a statement is made that these other patents or publications are cumulative. The examiner will then consider only the patent or publication of which a copy is submitted and will so indicate on the list, form PTO-1449, or PTO/ SB/08A and 08B, submitted, e.g., by crossing out the listing of the cumulative information. But see Semiconductor Energy Laboratory Co. v. Samsung Electronics Co., 204 F.3d 1368, 1374, 54 USPQ2d 1001, 1005 (Fed. Cir. 2000) (Reference was not cumulative since it contained a more complete combination of the claimed elements than any other reference before the examiner. "A withheld reference may be highly material when it discloses a more complete combination of relevant features, even if those features are before the patent examiner in other references." (citations omitted).).

37 CFR 1.98(a)(3)(ii) states that if a written English language translation of a non-English language document, or portion thereof, is within the possession, custody or control of, or is readily available to any individual designated in 37 CFR 1.56(c), a copy of the translation shall accompany the statement. Translations are not required to be filed unless they have been reduced to writing and are actually translations of what is contained in the non-English language information. If no translation is submitted, the examiner will consider the information in view of the concise explanation and insofar as it is understood on its face, e.g., drawings, chemical formulas, English language abstracts, in the same manner that non-English language information in Office search files is considered by examiners in conducting searches.

# <u>A (3)</u> Concise Explanation of Relevance for Non-English Language Information

Each information disclosure statement must further include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information listed that is not in the English language. The concise explanation may be either separate from the specification or incorporated therein with the page(s) and lines of the specification where it is incorporated being noted in the IDS.

The requirement for a concise explanation of relevance is limited to information that is not in the English language. The explanation required is limited to the relevance as understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information at the time the information is submitted to the Office. If a complete translation of the information into English is submitted with the non-English language information, no concise explanation is required. An English-language equivalent application may be submitted to fulfill this requirement if it is, in fact, a translation of a for eign language application being listed in an information disclosure statement. There is no requirement for the translation to be verified. Submission of an English language abstract of a reference may fulfill the requirement for a concise explanation. Where the information listed is not in the English language, but was cited in a search report or other action by a foreign patent office in a counterpart foreign application, the requirement for a concise explanation of relevance can be satisfied by submitting an English-language version of the search report or action which indicates the degree of relevance found by the foreign office. This may be an explanation of which portion of the reference is particularly relevant, to which claims it applies, or merely an "X", "Y", or "A" indication on a search report. The requirement for a concise explanation of non-English language information would not be satisfied by a statement that a reference was cited in the prosecution of a United States application which is not relied on under 35 U.S.C. 120.

If information cited or submitted in a prior application relied on under 35 U.S.C. 120 was not in English, a concise explanation of the relevance of the information to the new application is not required unless the relevance of the information differs from its relevance as explained in the prior application. 1 family member for: BE775775 Derived from 1 application.

Family Search Kesults for BE 775775

OLIGOPEPTIDES CONTENANT DE LA M-(DI-(2-CHLORETHYL)AMINO)-L-PHENYLALANINE.

Inventor:

EC:

Applicant: BELFANTI IST SIEROTERAP MILAN; I

IPC: C07C; A61K

Publication info: BE775775 A1 - 1972-03-16